UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,226	12/20/2001	Ranjani V. Parthasarathy	57313US002	9039

32692 7590 07/03/2003

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	9

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/027,226	Parthasarathy et al.
Examiner	**Art Unit**
Dwayne K. Handy	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above, claim(s) *1-49 and 56-61* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *50-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4, 7*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-49, drawn to methods of removing small negatively charged particles from a sample, classified in class 436, subclass 175.

II. Claims 50-55, drawn to a device for removing small negatively charged particles from a sample, classified in class 422, subclass 102.

III. Claims 56-61, drawn to a container with an adhesive cover for removing small negatively charged particles from a sample, classified in class 220, subclass 359.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II/III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used for performing multiple independent chemical reactions in array form.

3. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions have different modes of operation. Invention II appears to claim a device with a plurality of process arrays, each comprised of a plurality of chambers defining a volume and connected by a distribution channel. Invention III appears to claim a container covered by an adhesive. Invention II, then, would comprise a device which also processes the sample in addition to simply holding it in a container. This would be a different mode of operation.

4. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group II, restriction for examination purposes as indicated is proper.

5. In response to a Restriction in a previous Office Action, a provisional election was made with traverse to prosecute the invention of a device for removing small negatively charged particles from a sample, claims 50-55. Affirmation of this election was made by applicant in replying to this Office action. Claims 1-49 and 56-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The Examiner has re-written the Restriction requirement. The new requirement includes only 3 groups and no election of species in the method claims. The Examiner did, however, restrict between the two devices. The Examiner assumes applicant wishes to traverse the rewritten Restriction as well. Claims 50-55 have been Examined in this action.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

a timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. a terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 50-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending Application No. 10/417,609 in view of Dusterhoft et al. (6,451,260). Claims 53 and 56-58 of Application No. 10/417,609 teach every element of claims 50-53 except for a solid phase extraction material which comprises a hydrophilic solid support at least partially embedded within a hydrophobic matrix. Dusterhoft et al. teach a method of making microporous elements for use as filters and membranes in microfiltration, chromatography, adsorption and immobilization of organic and inorganic compounds. The reference also teaches methods of using the microporous elements as well. The microporous elements of Dusterhoft are best shown in Figures 1-5 and described in columns 23. The embodiment of the microporous matrix most relevant to the instant claims is described in columns 10 and 11:

(68) The method of the present invention for producing a filter element by generating a microporous element can be performed, e.g. within an aperture of a solid moisture-impervious support, comprising the steps of providing a solution of a synthetic or semi-synthetic polymer (resin) in a solvent; applying the solution to the aperture so as to form a self-sustaining liquid layer over the cross-section of the aperture; and causing a nonsolvent to diffuse into the layer, which nonsolvent is miscible with the solvent, whereby the resin precipitates to form the microporous element.

(69) Preferably the resin is selected from the group consisting of polyvinyl esters, partially deacylated polyvinyl esters, cellulose derivatives, polyamides, and mixtures thereof. Among polyvinyl esters polyvinyl acetate, polyvinyl propionate, polyvinyl stearate, and polyvinyl cinnamic acid ester; among cellulose derivatives nitrocellulose, and cellulose propionate are to be mentioned. a suitable polyamide is Nylon 6/6.

(70) **In certain instances, the resin preferably comprises both hydrophilic and hydrophobic segments within its molecules**. Suitable resins include poly(vinyl alcohol-co-ethylene), poly(vinyl alcohol-co-vinylacetate), ethylene acrylic acid copolymer, ethylene acrylic ester copolymer, ethylene acrylamide copolymer, acrylic acid vinylacetate copolymer, acrylamide vinylacetate copolymer, copolymer of acrylic acid diamine monoamide with vinylacetate, poly(vinyl alcohol-co-styrene), acrylamide acrylic.

ester copolymer, and mixtures thereof. Specifically, copolymers of acrylamide with hexyl acrylate, propyl acrylate or dodecyl acrylate are useful....

(76) Without intending to be bound to theory it is believed that in generating the microporous element according to the present invention the following mechanisms are involved: When the nonsolvent diffuses into the layer of resin solution, the solubility of the resin is gradually decreased. As the limit of solubility is reached the resin begins to precipitate from the solution at individual points. The precipitation of the resin proceeds at the points of initial precipitation. Ultimately, the solvent/nonsolvent is enclosed in large interconnecting enclaves in a solid matrix of resin. The interconnecting enclaves form the liquid-permeable channels of the final microporous element. **If a synthetic resin is used which comprises both hydrophilic and hydrophobic segments, the hydrophobic segments will be forced towards each other and brought into contact with each other as the concentration of nonsolvent in the resin solution increases. There will be interactions between the hydrophobic segments of neighboring molecule chains, which result in the formation of a crystalline hydrophobic backbone of the precipitated resin. The hydrophilic segments will be oriented towards the enclaves filled with solvent/nonsolvent. Accordingly, a microporous element is obtained where the liquid-permeable channels are predominantly hydrophilic. This provides the benefit of biocompatibility. The term "biocompatibility" means that the three-dimensional structure of biopolymers, for example proteins, peptides, nucleic acids, oligonucleotides, polysaccharides or derivatives thereof, is maintained.** The interphase forces are less destructive when the polymer surface is rich in hydroxyl, amide or ether groups.

It would have been obvious to one of ordinary skill in the art to combine the material comprised of a hydrophilic solid support at least partially embedded within a hydrophobic matrix from Dusterhoft with the device of Application No. 10/417,609. One would add the material from Dusterhoft to obtain the benefits of biocompatibility which allows the separation of specific biomolecules.

This is a provisional obviousness-type double patenting rejection.

9. Claims 50-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-42 of copending

Application No. 10/027,222 in view of Dusterhoft et al. (6,451,260). Claims 39-42 of copending Application No. 10/027,222 teach every element of claims 50-53 except for a solid phase extraction material which comprises a hydrophilic solid support at least partially embedded within a hydrophobic matrix. Dusterhoft et al. teach a method of making microporous elements for use as filters and membranes in microfiltration, chromatography, adsorption and immobilization of organic and inorganic compounds. Referring to the arguments and cited passages from Dusterhoft in paragraph 8 above, it would have been obvious to one of ordinary skill in the art to combine the material comprised of a hydrophilic solid support at least partially embedded within a hydrophobic matrix from Dusterhoft with the device of Application No. 10/027,222. One would add the material from Dusterhoft to obtain the benefits of biocompatibility which allows the separation of specific biomolecules.

This is a provisional obviousness-type double patenting rejection.

Inventorship

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,344,326) in view of Dusterhoft et al. (6,451,260). Nelson et al. teach a microfluidic device

for nucleic acid separation and processing. The device is comprised of a number of channels containing fluid control elements and separation media disposed on a substrate. The basic embodiment of the device is described in columns 4 and 5 and includes inlet and outlet passages as well as channels for distributing solutions through the various channels of the device. Nelson teaches the use of separation media in conjunction with the channels in column 8:

(15) Suitable capture media for proteins include the following. Suitable capture media for proteins include: ion exchange resins, including anion (e.g., DEAE) and cation exchange; hydrophobic interaction compounds (e.g., C4, C8 and C18 compounds); sulfhydryls; heparins; inherently active surfaces (e.g., plastics, nitrocellulose blotting papers); activated plastic surfaces; aromatic dyes such as Cibacron blue, Remazol orange, and Procion red. For carbohydrate moieties of proteins, lectins, immobilized hydrophobic octyl and phenylalkane derivatives can be suitable. For enzymes, analogs of a specific enzyme substrate-product transition-state intermediate can be suitable; for kinases, calmodulin can be suitable. Suitable capture media for receptors include receptor ligand affinity compounds.

(16) As mentioned above, the enrichment channel will comprise at least one inlet and at least one outlet. Of course, where there is a single inlet, the inlet must serve to admit sample to the enrichment channel at an enrichment phase of the process, and to admit an elution medium during an elution phase of the process. And where there is a single outlet, the outlet must serve to discharge the portion of the sample that has been depleted of the fraction retained by the enrichment media, and to pass to the main electrophoretic microchannel the enriched fraction during the elution phase. Depending on the particular enrichment means housed in the enrichment channel, as well as the particular device configuration, the enrichment channel may have more than one fluid inlet, serving as, e.g., sample inlet and elution buffer inlet; or the enrichment channel may have more than one outlet, serving as, e.g., waste outlet and enriched fraction fluid outlet. Where the enrichment channel is in direct fluid communication with the main electrophoretic channel, i.e., the enrichment channel and main electrophoretic flowpath are joined so that fluid flows from the enrichment channel immediately into the main electrophoretic flowpath, the enrichment channel will comprise, in addition to the waste outlet, an enriched fraction fluid outlet through which the enriched fraction of the sample flows into the main electrophoretic flowpath. When convenient, e.g., for the introduction of wash and/or elution solvent into the enrichment channel, one or more additional fluid inlets may be provided to conduct such solvents into the enrichment channel from fluid reservoirs. To control bulk fluid flow through the enrichment channel, e.g., to prevent waste sample from flowing into the main electrophoretic flowpath, fluid control means, e.g., valves, membranes, etc., may be associated with each of the inlets and outlets. Where desirable for moving fluid and entities through the enrichment channel, e.g., sample, elution buffer, reagents, reactants, wash or rinse solutions, etc., electrodes may be provided capable of applying an electric field to the material and fluid present in the enrichment channel.

(17) The next component of the subject devices is the main electrophoretic flowpath. The main electrophoretic flowpath may have a variety of configurations, including tube-like, trench-like or other convenient configuration, where the cross-sectional shape of the flowpath may be circular, ellipsoid, square, rectangular, triangular and the like so that it forms a microchannel on the surface of the planar substrate in which it is present. The microchannel will have cross-sectional area which provides for capillary fluid flow through the microchannel, where at least one of the cross-sectional dimensions, e.g., width, height, diameter, will be at least about 1 mm, usually at least about 10 mm, but will not exceed about 200 mm, and will usually not exceed about 100 mm. Depending on the particular nature of the integrated device, the main electrophoretic flowpath may be straight, curved or another convenient configuration on the surface of the planar substrate.

Nelson, then, teaches a device with a plurality of process arrays with a plurality of process chambers with solid phase separation media connected by a channel with a valve. Nelson also shows embodiments in which the arrays are arranged radially on the device. Nelson does not teach a solid phase extraction material which comprises a hydrophilic solid support at least partially embedded within a hydrophobic matrix. Dusterhoft et al. teach a method of making microporous elements for use as filters and membranes in microfiltration, chromatography, adsorption and immobilization of organic and inorganic compounds. The reference also teaches methods of using the microporous elements as well. The microporous elements of Dusterhoft are best shown in Figures 1-5 and described in columns 23. The embodiment of the microporous matrix most relevant to the instant claims is described in columns 10 and 11:

(68) The method of the present invention for producing a filter element by generating a microporous element can be performed, e.g. within an aperture of a solid moisture-impervious support, comprising the steps of providing a solution of a synthetic or semi-synthetic polymer (resin) in a solvent; applying the solution to the aperture so as to form a self-sustaining liquid layer over the cross-section of the aperture; and causing a nonsolvent to diffuse into the layer, which nonsolvent is miscible with the solvent, whereby the resin precipitates to form the microporous element.

(69) Preferably the resin is selected from the group consisting of polyvinyl esters, partially deacylated polyvinyl esters, cellulose derivatives, polyamides, and mixtures thereof. Among polyvinyl esters polyvinyl acetate, polyvinyl propionate, polyvinyl stearate, and polyvinyl cinnamic acid ester; among cellulose derivatives nitrocellulose, and cellulose propionate are to be mentioned. a suitable polyamide is Nylon 6/6.

(70) **In certain instances, the resin preferably comprises both hydrophilic and hydrophobic segments within its molecules**. Suitable resins include poly(vinyl alcohol-co-ethylene), poly(vinyl alcohol-co-vinylacetate), ethylene acrylic acid copolymer, ethylene acrylic ester copolymer, ethylene acrylamide copolymer, acrylic acid vinylacetate copolymer, acrylamide vinylacetate copolymer, copolymer of acrylic acid diamine monoamide with vinylacetate, poly(vinyl alcohol-co-styrene), acrylamide acrylic ester copolymer, and mixtures thereof. Specifically, copolymers of acrylamide with hexyl acrylate, propyl acrylate or dodecyl acrylate are useful....

(76) Without intending to be bound to theory it is believed that in generating the microporous element according to the present invention the following mechanisms are involved: When the nonsolvent diffuses into the layer of resin solution, the solubility of the resin is gradually decreased. As the limit of solubility is reached the resin begins to precipitate from the solution at individual points. The precipitation of the resin proceeds at the points of initial precipitation. Ultimately, the solvent/nonsolvent is enclosed in large interconnecting enclaves in a solid matrix of resin. The interconnecting enclaves form the liquid-permeable channels of the final microporous element. **If a synthetic resin is used which comprises both hydrophilic and hydrophobic segments, the hydrophobic segments will be forced towards each other and brought into contact with each other as the concentration of nonsolvent in the resin solution increases. There will be interactions between the hydrophobic segments of neighboring molecule chains, which result in the formation of a crystalline hydrophobic backbone of the precipitated resin. The hydrophilic segments will be oriented towards the enclaves filled with solvent/nonsolvent. Accordingly, a microporous element is obtained where the liquid-permeable channels are predominantly hydrophilic. This provides the benefit of biocompatibility. The term "biocompatibility" means that the three-dimensional structure of biopolymers, for example proteins, peptides, nucleic acids, oligonucleotides, polysaccharides or derivatives thereof, is maintained.** The interphase forces are less destructive when the polymer surface is rich in hydroxyl, amide or ether groups.

It would have been obvious to one of ordinary skill in the art to combine the material comprised of a hydrophilic solid support at least partially embedded within a hydrophobic matrix from

Dusterhoft with the device of Nelson et al. One would add the material from Dusterhoft to obtain the benefits of biocompatibility which allows the separation of specific biomolecules.

14. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,344,326) and Dusterhoft et al. (6,451,260) as applied to claims 50-53 above, and further in view of Chisolm (4,399,009). Nelson and Dusterhoft, as described above, teach every element of claims 54 and 55 except for the adhesive matrix and a pattern of particles coated on the matrix. Chisholm teaches an electrolytic cell which contains a semipermeable membrane for coating the electrodes of the cell and separating . The membrane is in sheet form and normally comprises a layer, coating or sheet of a fluorocarbon having cation exchange groups and a second layer which is non-fluorinated or less fluorinated. The layers are held together and in place on the electrode through the use of an adhesive applied to both the hydrophobic and hydrophilic portions (Abstract, column 4 - lines 6-22). It would have been obvious to one of ordinary skill in the art to combine the adhesive from Chisholm with the combined teachings of Nelson and Dusterhoft. The addition of adhesive to the separation media from Nelson and Dusterhoft would allow one to bind the media to the channel containing the media and keep the media in place during use of the device.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swedberg et al. (6,450,047), Gjerde et al. (6,265,168), Muscate-Magnussen (US 2002/0046966), Ingenhoven et al. (US 2002/0182114), Zare et al. (2003/0062310), Gundel et al. (2001/0045000), Jedrzejewski et al. (2003/0013203), and Andersson et al. (2003/0053934) teach separation devices which use solid phase extraction media.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

dkh

June 29, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700